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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,774	02/07/2005	Nobutaka Wakamiya	19036/40320	5088

4743 7590 05/01/2007
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EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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05/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,774

Applicant(s)

WAKAMIYA ET AL.

Examiner

Louise Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 18-37, 39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/25/05, 11/26/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The Office acknowledges the receipt of Applicant's election and Amendment, filed on 7 February 2007.

Election/Restriction

Applicant's election of Group I, claims 1-17 and 38, in the reply filed on 7 February 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The species election is withdrawn upon a search of prior art.

Claims 1-40 are pending. Claims 18-37, 39 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Claims 1-17 and 38 are examined.

Priority

Applicant's submission under 35 U.S.C. §119(a)-(d) of the foreign priority document, JAPAN 2002-189534, is acknowledged. However, English translations of the priority document have not been provided. Therefore, it is not clear whether the foreign priority documents provide written description for the instant claims.

Therefore, the priority date is deemed to be the filing date of the priority application PCT/JP03/08259 (06/30/2003).

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS form 1449, filed on 26 November 2004 and 25 April 2005, respectively, are attached to the instant Office action.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 38 is rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. MBP is a naturally occurring protein. However, the claim simply recites "a mannose binding protein (MBP)," which fails to distinguish over the naturally occurring protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 and 38 are rejected under 35 U.S.C. §102(b) as being anticipated by Ezekowitz *et al.* (1989, cite no. C1 in IDS filed 26 November 2004).

Claim 1 is directed to an anti-HIV agent which comprises a mannose binding protein (MBP) as an active component. Claims 2-4 and 38 are drawn to MBP having

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HIV neutralization and HIV budding suppressive activity. Claims 5-7 are drawn to MBP from various sources. Claims 8-17 are drawn to MBP suppressing HIV of different tropisms, subtypes, and strain.

Ezekowitz *et al.* teach that MBP can inhibit HIV infection of H9 lymphoblasts at physiologically relevant concentrations, and that MBP binds selectively to HIV-infected cells. See Abstract. Human MBP was purified from human plasma from patients undergoing plasmapheresis. See page 186, Materials and Methods.

Since Ezekowitz *et al.* specifically teach that the ligand for MBP binding is the mannose oligosaccharides on gp120 (Abstract) and gp120 is present in every strain of HIV-1 regardless of the cell tropism, the MBP must inherently inhibit every subtype or strain of HIV of any kind of tropism in claims 8-17.

Claims 5-7 are product-by-process claims and are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP § 2113: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Since Ezekowitz *et al.* teach the claimed MBP, the MBP from different sources in claims 5-7 are anticipated.

Claims 2-4 and 38 are drawn to the properties of HIV neutralization and HIV budding suppression. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1251, 1254, 195 USPQ 430, 433 (CCPA 1977). See M.P.E.P. §2112 [R-3] I. Since Ezekowitz *et al.* teach the claimed MBP, the HIV suppressive functions recited in claims 2-4 and 38 are inherently taught by Ezekowitz *et al.*

Thus, the instant invention is anticipated by Ezekowitz *et al.*

Remarks

No claim is allowable.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP §714.02 and §2163.06.

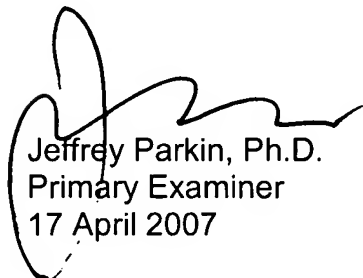
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Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.
Primary Examiner
17 April 2007

Louise Humphrey, Ph.D.
Assistant Examiner